

## ***Appendix E***

### ***TDH Regulatory Review***



## TDH Regulatory Review

### PART 1 – Explanation of Context and Background

#### I. Statement of Charge

HB 2085 Section 1.23.

- (a) The Texas Department of Health, with the assistance of the state auditor, shall conduct a comprehensive evaluation of the department's regulatory functions. The evaluation must include an examination and analysis of the effectiveness of the department's:
  - (1) rules that affect or support its regulatory practices;
  - (2) inspection efforts, including its scheduling of inspections and consistency between inspections;
  - (3) investigative practices, including investigation conducted in response to a complaint;
  - (4) use of sanctions;
  - (5) enforcement actions in relation to the time it takes to initiate and complete an enforcement action and in relation to the role of the department's office of general counsel;
  - (6) efforts to ensure compliance with applicable laws and rules; and
  - (7) efforts to ensure the consistency and appropriateness of the training of inspectors, including ensuring that:
    - (A) inspectors are familiar with the type of facility and with the type of care provided at a facility that they inspect; and
    - (B) the skills and knowledge of inspectors remain current through continuing education and review.
- (b) The department shall report the results of the evaluation, including the identification of any problem areas and any recommended solutions to the problems that require management actions or statutory changes, to the legislature and to the Texas Board of Health not later than November 1, 2000.

## II. Explanation of Context

### A. *Why was TDH given this charge?*

TDH was given this charge because the Sunset Advisory Commission staff did not have enough time to do a comprehensive evaluation of TDH's regulatory programs. "Although a full investigation of the 55 regulatory programs was not possible, Sunset staff found enough significant concerns to recommend TDH conduct a comprehensive evaluation of its regulatory functions with assistance from the State Auditor's Office." (TDH Sunset Advisory Commission Staff Report, p.13, 1998)

### B. *History*

Some of TDH's programs have been individually evaluated internally and externally, but the department has never done a comprehensive evaluation of all of its programs at the same time. The last external evaluations were done by the State Auditor's Office in 1997-1998 and focused on TDH's Professional Licensing and Certification Division and Home Health Program.

### C. *Who will benefit from TDH's Regulatory Review?*

Consumers, the regulated community, and TDH will all benefit from a comprehensive evaluation aimed at strengthening the department's regulatory programs.

### D. *Current system*

Over the last 80 years, TDH's regulatory responsibilities have evolved to include 69 programs in mainly two Associateships - Health Care Quality and Standards and Environmental and Consumer Health. Among these programs are eleven independent professional licensing boards which are administratively attached to TDH, but which have independent rule-making authority. Fifteen divisions in five bureaus administer these 69 programs, which regulate a wide variety of approximately 250,000 professionals, facilities, and businesses that provide goods and services to 20 million Texas consumers, which potentially affect public health. The primary purpose of these programs is to prevent illnesses and injuries by assuring that these regulated

entities comply with applicable rules and statutes. TDH regulatory programs ensure compliance mainly through inspections, investigation of complaints, using enforcement sanctions, and licensing and certification.

## **Associateship for Health Care Quality and Standards**

### *Bureau of Licensing and Compliance*

#### Health Facilities Licensing Division

- Abortion Facility Licensing
- Ambulatory Surgical Center Licensing
- Birthing Center Licensing
- End Stage Renal Disease Facility Licensing
- General and Special Hospital Licensing
- Private Psychiatric Hospitals Licensing/Crisis Stabilization Units Licensing
- Special Care Facility Licensing

#### Professional Licensing and Certification Division

- Athletic Trainer Licensing \*
- Contact Lens Dispensing Permit/Registry
- Dietitian Licensing \*
- Fitting and Dispensing of Hearing Instruments Licensing \*
- Health Related Services Registry (voluntary)
- Marriage and Family Therapist Licensing \*
- Massage Therapy Registration
- Medical Radiologic Technologist Licensure
- Medical Physicist Licensure \*
- Midwifery Documentation
- Optician Registration
- Orthotics and Prosthetics Licensing \*
- Perfusionist Licensing \*
- Professional Counselor Licensing \*
- Professional Social Worker Licensing \*
- Respiratory Care Practitioners Certification
- Sex Offender Treatment Provider Registration \*
- Speech Language Pathology and Audiology Licensing

\* Independent board

*Bureau of Emergency Management Services*

- EMS Provider Licensing
- EMS Personnel Certification
- Trauma Center Designation (voluntary)

**Associateship for Environmental & Consumer Health**

*Bureau of Environmental Health*

General Sanitation Division

- Certified public health pesticide applicators
- Code enforcement officers
- Migrant labor housing
- Registered sanitarians
- Youth camps

Product Safety Division

- Abusable glues and aerosol paint retailers
- Bedding product manufacturers
- Hazardous consumer product manufacturers

Toxic Substances Control Division

- Asbestos health protection
- Environmental lead
- Hazard communication

*Bureau of Food & Drug Safety*

Drugs and Medical Devices Division

- Device manufacturers
- Device wholesalers and distributors
- Drug manufacturers
- Drug wholesalers and distributors
- Drug, device and cosmetic salvage establishments
- Limited drug and device retail distribution
- Narcotic treatment programs
- Tanning salons
- Tattoo studios
- Body piercing studios

Manufactured Foods Division

- Bottled and vended water operators
- Food manufacturers
- Food salvage establishments
- Wholesale food distributors

Meat Safety Assurance Division

- Meat plants
- Poultry plants
- Rendering

Milk and Dairy Products Division

- Bulk milk haulers
- Frozen dessert manufacturers
- Milk Producers
- Milk Processors

Retail Foods Division

- Food service workers and training programs (voluntary)
- Retail food establishments

Seafood Safety Division

- Crab meat plants
- Molluscan shellfish

*Bureau of Radiation Control*

- Industrial radiography
- Lasers (non-ionizing)
- Mammography Facility Certification
- Radioactive materials
- X-ray (radiation-producing machines)

E. *Key assumptions and challenges*

The key assumptions critical to TDH's Regulatory Review include:

- TDH regulatory programs are designed to protect public health and safety;
- Review will include only TDH programs that are primarily regulatory;
- Independent licensing boards administratively attached to TDH will be included in the review;
- Stakeholder input is an integral part of the review process;
- Review precedes possible reorganization of the regulatory areas; and
- Validity of report recommendations will be based on the process we use for the review.

The main challenges in TDH's Regulatory Review include:

- Wide diversity of TDH's regulatory programs;
- Defining and measuring effectiveness;
- Including industry and public in the process;
- Obtaining buy-in from all levels;
- Gathering quality and useful information in the program review;  
and
- Degree of other state agency involvement, such as Health & Human Services Commission and State Auditor's Office.

*F. How should TDH's regulatory programs be changed?*

The Sunset Commission and the Texas Legislature clearly charged TDH to "strengthen enforcement activities through re-engineering and improved sanctions" (Issue 3 title, Sunset Advisory Commission Staff Report, p. 43, 1998). TDH's Regulatory Review should lead to specific management and statutory recommendations that will:

- Strengthen enforcement activities and ensure compliance;
- Improve consistency of regulatory functions statewide and across programs;
- Streamline regulatory functions to be more efficient and user-friendlier; and
- Ensure adequate training of technical staff and the necessary enforcement tools.

## **PART 2 – DESCRIPTION OF PROCESS**

### **I. Process**

*A. Annotated timeline (see Table E-1).*

*B. Information gathered and processed*

The RRTF developed three survey tools to gather information to evaluate TDH's regulatory programs (survey tools are available upon request):



Table E-1. Annotated Timeline in Completing the Review

Steps Taken in Process of Completing Charge	Dates of Activity & Completion	Staff Responsible
TDH Regulatory Review Task Force (RRTF) was organized and consists of HCQS, ECH, OGC, Internal Audit. RRTF has met almost every other week since August 1999.	August – October 1999	RRTF
RRTF established a 3 tier process for conducting program reviews: 1) internal self-assessment tool, 2) stakeholder survey, 3) licensee survey.	October 1999	RRTF
RRTF developed internal self-assessment tool with input and review from program and field staff.	September - October 1999	RRTF
RRTF briefed Board of Health, State Auditor, Sunset Advisory Commission, and legislative leadership staff and obtained feedback.	October – November 1999	RRTF
RRTF initiated and completed a pilot of internal self-assessment tool with 4 programs and 1 region. RRTF developed the stakeholder/licensee survey.	November – December 1999	RRTF
RRTF briefed other legislative staff and stakeholders and obtained feedback.	December 1999	RRTF
RRTF established a website to make information about the evaluation readily available to the public, regulated community, and TDH staff.	January 2000	RRTF
RRTF distributed internal self-assessment, stakeholder, and licensee surveys.	January 2000	RRTF
Completed internal self-assessment, stakeholder, and licensee surveys were collected.	March 2000	RRTF
RRTF compiled and analyzed survey data.	April – June 2000	RRTF
RRTF drafted a report including cross-cutting issues and recommendations, and specific program analyses and recommendations. RRTF completed and posted the draft report on the website for public comment in mid-July.	June – July 2000	RRTF
RRTF reviewed draft report and public comments and obtained input from TDH senior management.	July – August 2000	RRTF
RRTF will present revised draft report to BOH.	September 2000	RRTF
RRTF will submit final report with public comments to BOH and Legislature.	November 1, 2000	RRTF
RRTF will develop Blueprint objectives and begin implementing management recommendations.	November – December 2000	RRTF

- *Internal self-assessment tool* - a 40 page detailed narrative self-assessment audit survey was completed by TDH central office and regional staff in each regulatory program area and region;
- *Stakeholder survey* – a three-page survey (combination Likert scale questions with scannable answer sheet and narrative questions) was sent to a wide variety of professional and industry trade associations, advocacy organizations, and other agencies to obtain stakeholder input (975 distributed, 15 percent response rate);
- *Licensee survey* – a three-page survey identical to the stakeholder was sent to a representative sample of each regulatory program to obtain licensee input (1588 distributed, 16 percent response rate); and
- The stakeholder/licensee survey was also posted on the RRTF website by the University of Texas at Austin so that anyone could respond on-line to the survey.

The questions and format of these three surveys paralleled the seven specific areas that the Legislature instructed to TDH to evaluate and also included questions on licensing activities. Licensing was added to the RRTF's overall evaluation because it is a large part of TDH's regulatory activities. The eight major areas in the surveys and eventually the final report are:

- Rules/statutes,
- Inspection efforts,
- Investigative practices,
- Use of sanctions,
- Compliance efforts,
- Enforcement actions including timeliness,
- Technical staff and training, and
- Licensing activities.

Frequencies were run on the stakeholder and licensee survey data. Central office senior program management summarized the narrative data from all survey and the stakeholder/licensee frequencies. This was done by program in each of the eight major areas using the following outline:

- Summary of Internal Assessment,
- Analysis of Stakeholders/Licensee Surveys,
- Conclusions and Problem Areas Identified, and
- Recommendations
  - o Management and
  - o Statutory.

From these program summaries, draft cross-cutting issues that applied to multiple programs were identified. The RRTF then convened program and regional staff to brainstorm recommended solutions to address these issues. From this information, the final report will: 1) identify both cross-cutting and program-specific issues and problems and 2) recommend management actions or statutory changes to address those issues and problems.

### **PART 3 – GOALS AND OBJECTIVES**

The findings and recommendations in the final TDH Regulatory Review report due to the Board of Health and Legislature by November 1, 2000 will translate into objectives for the goal below.

**GOAL 1:** TDH will strengthen its regulatory activities through re-engineering and improved sanctions.

